



Advanced Development of Chem-Bio Medical Countermeasures for the DoD

Armed Forces Epidemiology Board

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Agenda



- Organization
 - Chem Bio Defense Program
 - Chemical Biological Medical Systems (CBMS)
- Challenges in DoD Medical CBD Acquisition
- Joint Vaccine Acquisition Program (JVAP)
- Medical Identification and Treatment Systems (MITS)
- Conclusion



Chem/Bio Defense Program Acquisition Organizations



Requirements

Joint Requirements Office

Science & Technology

Defense Threat Reduction Agency -Chem/Bio Directorate

Test & Evaluation

Test & Evaluation Executive

(DUSA-OR)

Defense Acquisition Executive

(USD-ATL)

Army Acquisition Executive

(ASA-ALT)

Joint Program
Executive
Officer

Joint Project Managers

50 USC 1522

OSD Oversight

ATSD (NCB)

DATSD (CB)

Joint Doctrine & Training

Joint Staff

US Army Chemical School



System of Systems Approach



Counter the Threat

Sustained Combat Power

CB Threats & Hazards

Doses on

Doses Downwind Absorbed

Dispersal

Symptoms ?

Agent **Delivery Target**



Contamination Avoidance and

NBC Battle

(Detection,

Management

Medical Pretreatment



Individual & Collective Protection



Installation Force Protection



Medical Treatment



Information Systems



Decontamination, Restoration

JPE-CBD

Chemical Biological Medical Systems (CBMS)



Joint Program Executive Officer

Joint Project Mgr CBMS

Joint Product Mgr JVAP Joint Product Mgr MITS



CBMS Mission



Develop, procure, field, and sustain premier <u>medical protection</u> <u>and treatment capabilities</u> against chemical and biological warfare agents.





Medical Acquisition Strategy



- Addresses user <u>requirements</u> based on Chairman of the Joint Chiefs of Staff priorities
- Develops <u>FDA licensed</u> chemical and biological defense (CBD) medical products
- <u>Leverages</u> international partnerships, other government agencies, and industry
- Manages product line <u>within available</u> <u>resources</u>
 - Funds product development efforts to <u>minimize schedules</u>
 - Expands or contracts product line based on available funding



Industry Standard



- Industry trend:
 - Clinical trial development times are increasing
 - 4 yrs in early 1990's to 6+ years in early 2000's
- CBMS projected clinical trial development times are:
 - Botulism vaccine = 6 yrs (FDA Licensure: FY12)
 - Plague vaccine = 5 yrs (FDA Licensure: FY10)
 - Advanced Anticonvulsant System = 7 yrs (FDA Approval FY11)
- CBMS schedules are in line with industry standard
- CBMS continues to explore ways to shorten schedules



JVAP Mission



Aggressively develop, produce, and stockpile *FDA licensed vaccine systems* to protect the Warfighter from biological agents.



JPE -CBD **JVAP: Meeting Warfighter** Needs **FY11 FY04 FY05 FY06 FY07 FY08 FY09 FY10** Licensure **DoD Funded Programs AVA** In Production -6 mos 18 Feb 05 **VIG** MS C BOT (A/B) 2012 MŠ B MS C **Plague** 2010 MS C MS B 2013 VEE MS B **DHHS Programs** Smallpox **VIG NGAV** BOT (CEF) Don Unfunded Programs Rica **TBD** SE **TBD** IND **Initiate Initiate Phase** Initiate BLA Licensur **LEGEND:** Mileston Submissio Phase 1 **2 Clinical Trial Submission** Phase 3 **Clinical Trial** Clinical Trial NDA Transition Submission

Highlights show FY04-FY05 changes

JPE®-CBDMedical Identification & Treatment Systems



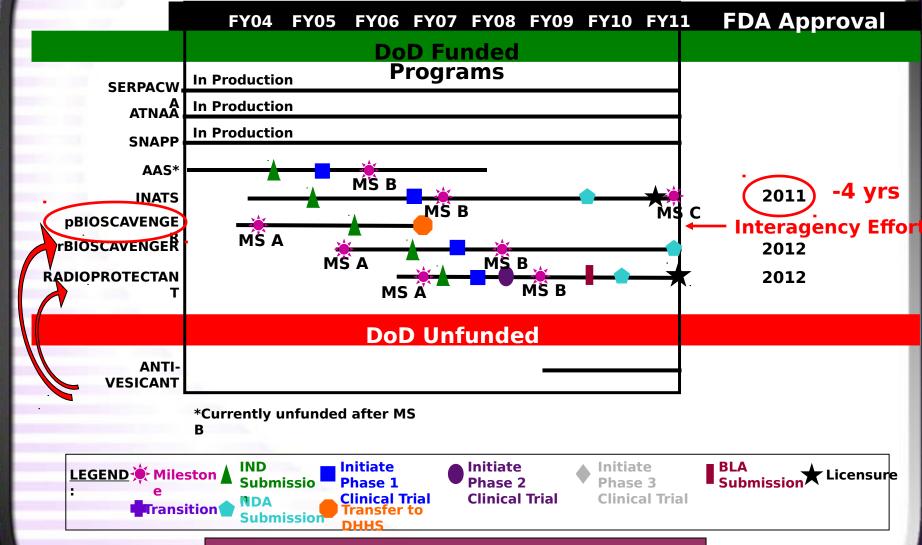
Develop and acquire safe, effective, and FDA-approved products for prophylaxis, treatment, and diagnosis of chemical and biological warfare agent exposure.



JPE -CBD

MITS: Meeting Warfighter Needs





Highlights show FY04-FY05 changes



DoD Medical Chem-Bio Projections



FY05

- VIG: FDA licensure Feb 18, 2005
- Plague & VEE: Submission of INDs & initiate Phase 1
 clinical trials
- Plague: Initiate Phase 2 clinical trial
- pBioscavenger: award process development, small-scale manufacturing, acute toxicology studies, and a Phase 1 clinical trial contract
- rBOT: Milestone B decision
- JBAIDS: LRIP and Initial Operational Capability

FY06

- Plague: Continue Phase 2 clinical trial
- VEE: Complete Phase 1 clinical trial; Milestone B decision
- rBOT: Initiate Phase 2 clinical trial
- rBioscavenger: Milestone A decision
- JBAIDS Block II: Milestone B decision



Take Aways



- CBMS program addressing DoD priority requirements
 - Focused on FDA licensure
 - Working within available resources
 - Leveraging Other Government Agencies and International partners
- CBMS acquisition strategy is in line with industry schedule standards for achieving medical product licensure
- CBMS continues to look for and find ways to shorten developmental schedules.



CHEMICAL BIOLOGICAL MEDICAL SYSTEMS



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